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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,517	12/02/2004	Kentaro Enjo	Q85059	8631

65565 7590 06/28/2007

SUGHRUE-265550
2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
06/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,517	ENJO ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 1984*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, drawn to the polypeptide of SEQ ID NO:2 or variants thereof.

Group II, claim(s) 2, drawn to cell expressing the polypeptide of SEQ ID NO:2 or variants thereof.

Group III, claim(s) 3, drawn a method for detecting whether or not a test compound is an inverse agonist using the cell described in claim 2 co-expressing a chimeric G protein.

Group IV, claim(s) 4, drawn a method for screening an agent for renal failure using the cell described in claim 2 co-expressing a chimeric G protein.

Group V, claim(s) 5 and 6, drawn a method for screening a substance inhibiting expression of CTGF, using the cell described in claim 2 expressing the DNA of SEQ ID NO:13 having a down stream reporter gene.

Group VI, claim(s) 7 , drawn a method for screening an agent for treating renal failure, using the cell described in claim 2 expressing the DNA of SEQ ID NO:I4 having a down stream reporter gene to contact with a test compound.

Group VII, claim(s) 8 , drawn a pharmaceutical composition for treating renal failure, which comprises an inverse agonist for the polypeptide described in claim I.

Group VIII, claim(s) 9 , drawn a pharmaceutical composition for treating renal failure, which comprises a substance obtainable by the method according of claim 4.

Group IX, claim(s) 9 , drawn a pharmaceutical composition for treating renal failure, which comprises a substance obtainable by the method according of claim 5.
Group X, claim(s) 9 , drawn a pharmaceutical composition for treating renal failure, which comprises a substance obtainable by the method according of claim 6.

Group XI, claim(s) 9 , drawn a pharmaceutical composition for treating renal failure, which comprises a substance obtainable by the method according of claim 7.

Group XII, claim(s) 10 , drawn a method for producing a pharmaceutical composition for treating renal failure, which comprises a step of screening using the method according to 4, and a step of preparing a pharmaceutical composition using a substance obtained by said screening.

Group XIII, claim(s) 10 , drawn a method for producing a pharmaceutical composition for treating renal failure, which comprises a step of screening using the method according to 5, and a step of preparing a pharmaceutical composition using a substance obtained by said screening

Group XIV, claim(s) 10 , drawn a method for producing a pharmaceutical composition for treating renal failure, which comprises a step of screening using the method according to 6, and a step of preparing a pharmaceutical composition using a substance obtained by said screening

Group XV, claim(s) 10 , drawn a method for producing a pharmaceutical composition for treating renal failure, which comprises a step of screening using the method according to 7, and a step of preparing a pharmaceutical composition using a substance obtained by said screening

Group XVI, claim(s) 11 , drawn a method for treating renal failure, which comprises administering an effective amount of an inverse agonist for the polypeptide described in claim 1 and/or a substance obtainable by the method according to claim 4 to a subject in need of the treatment of renal failure.

Group VII, claim(s) 11 , drawn a method for treating renal failure, which comprises administering an effective amount of an inverse agonist for the polypeptide described in claim 1 and/or a substance obtainable by the method according to claim 5 to a subject in need of the treatment of renal failure.

Group XVIII, claim(s) 11 , drawn a method for treating renal failure, which comprises administering an effective amount of an inverse agonist for the polypeptide described in claim 1 and/or a substance obtainable by the method according to claim 6 to a subject in need of the treatment of renal failure.

Group XIX, claim(s) 11 , drawn a method for treating renal failure, which comprises administering an effective amount of an inverse agonist for the polypeptide described in claim 1 and/or a substance obtainable by the method according to claim 7 to a subject in need of the treatment of renal failure.

Group XX, claim(s) 12 , drawn to use of an inverse agonist for the polypeptide described in claim 1 and/or a substance obtainable by the method according to claim 4 for the manufacture of a pharmaceutical composition for treating renal failure.

Group XXI, claim(s) 12 , drawn to use of an inverse agonist for the polypeptide described in claim 1 and/or a substance obtainable by the method according to claim 5 for the manufacture of a pharmaceutical composition for treating renal failure.

Group XXII, claim(s) 12 , drawn to use of an inverse agonist for the polypeptide described in claim 1 and/or a substance obtainable by the method according to claim 6 for the manufacture of a pharmaceutical composition for treating renal failure.

Group XXIII, claim(s) 12 , drawn to use of an inverse agonist for the polypeptide described in claim 1 and/or a substance obtainable by the method according to claim 7 for the manufacture of a pharmaceutical composition for treating renal failure.

2. The inventions listed as Groups I-XXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:.

3. The inventions listed as Groups I - XXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical feature for the following reasons. The special technical feature of Group I is the polypeptide of SEQ ID NO:2. The product claimed in Group I is the polypeptide of SEQ ID NO:2 or variants thereof in which from 1 to 10 amino acids are deleted, substituted and/or inserted and which is capable of activating CTGF promoter. Therefore the product of claim 1, the polypeptide of SEQ ID NO:2 is considered to constitute the main invention. Cor Therapeutics Inc.(WO 97/20045, June 1997) teach the special technical feature of Group 1, i.e. the polypeptide of SEQ ID NO:2. The polypeptide of SEQ ID NO:2 inherently is capable of activating CTGF promoter. A sequence comparison of the protein sequences in instant application and

in WO 97/20045 is provided below:

```
Run on:         June 12, 2006, 14:53:37 ; Search time 200 Seconds
                                          (without alignments)
                                          754.407 Million cell updates/sec

Title:          US-10-516-517-2
Perfect score:  1724
Sequence:       1 MAWNATCKNWLAAEAALEKY.........KSLTSFSRWAHELLLSFREK 330

Scoring table:  BLOSUM62
                Gapop 10.0 , Gapext 0.5

Searched:       2589679 seqs, 457216429 residues

Total number of hits satisfying chosen parameters:      2589679

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
                 Maximum Match 100%
                 Listing first 45 summaries

Database :       A_Geneseq_8:*
                1:  geneseqp1980s:*
                2:  geneseqp1990s:*
                3:  geneseqp2000s:*
                4:  geneseqp2001s:*
                5:  geneseqp2002s:*
                6:  geneseqp2003as:*
                7:  geneseqp2003bs:*
                8:  geneseqp2004s:*
                9:  geneseqp2005s:*
                10:  geneseqp2006s:*

     Pred. No. is the number of results predicted by chance to have a
     score greater than or equal to the score of the result being printed,
     and is derived by analysis of the total score distribution.

                                    SUMMARIES

                 %
Result           Query
   No.    Score  Match Length DB  ID                      Description
 ---------------------------------------------------------------------------
          2    1724  100.0    334  2  AAW19854                Aaw19854 Human pur
                                      ALIGNMENTS


RESULT 2
AAW19854
ID   AAW19854 standard; protein; 334 AA.
AC   AAW19854;
DT   11-SEP-1997  (first entry)
DE   Human purinergic receptor P2U2.
KW   P2U2 receptor; purinergic receptor; diagnosis; therapy.
OS   Homo sapiens.
PN   WO9720045-A2.
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PD   05-JUN-1997.
PF   08-NOV-1996;   96WO-US018175.
PR   15-NOV-1995;   95US-0006782P.
PR   15-NOV-1995;   95US-00559524.
PA   (CORT-) COR THERAPEUTICS INC.
PI   Conley PB,  Jantzen H;
DR   WPI; 1997-310601/28.
DR   N-PSDB; AAT71900.
PT   New isolated purinergic receptor sub-type - used to develop products for
PT   diagnosis and therapy, e.g. for screening for agonists and antagonists
PT   which can modulate activation.
PS   Claim 1; Fig 1A-B; 36pp; English.
CC   P2U2 receptor (AAW19854) is a novel human purinergic receptor subtype
CC   that is abundantly expressed in kidney and in many cell lines of
CC   megakaryocytic or erythroleukaemic origin and which is activated by ATP,
CC   UDP, UTP and UDP. Its amino acid sequence was deduced from a cDNA clone
CC   derived from DAMI (ATCC CRL 9792) cells. P2U2 and its polypeptides can be
CC   expressed in host cells and used to develop diagnostic and therapeutic
CC   agents. Antagonists and agonists based on the extracellular domains of
CC   P2U2 receptor, or which affect receptor function by binding to one of the
CC   intracellular domains, can be used to treat diseases caused by aberrant
CC   activation of this receptor or to treat diseases whose symptoms can be
CC   ameliorated by stimulating or inhibiting the activity of the receptor
XX
SQ   Sequence 334 AA;

  Query Match             100.0%;  Score 1724;  DB 2;  Length 334;
  Best Local Similarity   100.0%;  Pred. No. 5e-168;
  Matches  330;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MAWNATCKNWLAAEAALEKYYLSIFYGIEFVVGVLGNTIVVYGYIFSLKNWNSSNIYLFN 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          5 MAWNATCKNWLAAEAALEKYYLSIFYGIEFVVGVLGNTIVVYGYIFSLKNWNSSNIYLFN 64

Qy         61 LSVSDLAFLCTLPMLIRSYANGNWIYGDVLCISNRYVLHANLYTSILFLTFISIDRYLII 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         65 LSVSDLAFLCTLPMLIRSYANGNWIYGDVLCISNRYVLHANLYTSILFLTFISIDRYLII 124

Qy        121 KYPFREHLLQKKEFAILISLAIWVLVTLELLPILPLINPVITDNGTTCNDFASSGDPNYN 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        125 KYPFREHLLQKKEFAILISLAIWVLVTLELLPILPLINPVITDNGTTCNDFASSGDPNYN 184

Qy        181 LIYSMCLTLLGFLIPLFVMCFFYYKIALFLKQRNRQVATALPLEKPLNLVIMAVVIFSVL 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        185 LIYSMCLTLLGFLIPLFVMCFFYYKIALFLKQRNRQVATALPLEKPLNLVIMAVVIFSVL 244

Qy        241 FTPYHVMRNVRIASRLGSWKQYQCTQVVINSFYIVTRALGFLNSVINPVFYFLLGDHFRD 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        245 FTPYHVMRNVRIASRLGSWKQYQCTQVVINSFYIVTRALGFLNSVINPVFYFLLGDHFRD 304

Qy        301 MLMNQLRHNFKSLTSFSRWAHELLLSFREK 330
              ||||||||||||||||||||||||||||||
Db        305 MLMNQLRHNFKSLTSFSRWAHELLLSFREK 334
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Because the special technical feature of the invention has been found in the prior art, a technical relationship does not exist between the claimed groups. Therefore, unity

of invention is lacking. The methods of each group are materially different process steps; the process steps are the technical features which distinguish each method from the others. Because the process steps do not share the same or a corresponding special technical feature, unity of invention is lacking. The claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept. The products of are distinct from each other and from the methods because they are capable of separate use and manufacture e.g. the products can be use to produce antibodies. The product claims and method claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept. The inventions are drawn to patentably distinct methods and patentably distinct compounds.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in

accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nirmal S. Basi

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